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IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, INC. )

Plaintiff, )

v. )

1:02CV334

UNITED STATES ENVIRONMENTAL )  
PROTECTION AGENCY, )

CHRISTINE TODD WHITMAN, )  
Administrator, United States Environmental )  
Protection Agency, )

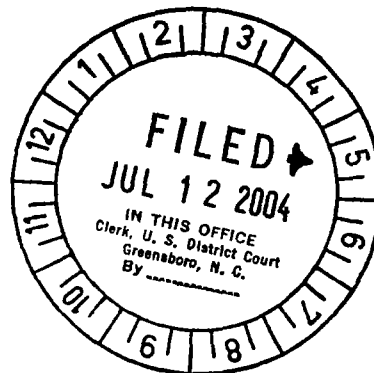
CEDAR CHEMICAL CORPORATION, )

TRI CHEMICALS, INC., )

SIPCAM AGRO USA, INC., )

DREXEL CHEMICAL COMPANY, )

Defendants. )



MEMORANDUM OPINION

TILLEY, Chief Judge

On April 29, 2002, Plaintiff Syngenta Crop Protection, Inc. ("Syngenta") filed suit against Defendants United States Environmental Protection Agency and its Administrator, Christine Todd Whitman (collectively "EPA"), Cedar Chemical Corp. ("Cedar"), TRI Chemicals, Inc. ("TRI"), Sipcam Agro USA, Inc. ("Sipcam"), and Drexel Chemical Company ("Drexel"). The Complaint seeks injunctive and declaratory relief and alleges that EPA issued pesticide registrations in violation of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136, et seq.

Numerous motions in this matter are now pending, the following of which are addressed in this Memorandum Opinion: Syngenta's Updated Motion for Leave to Amend and Supplement its Complaint [Doc. #120], Syngenta's Motion for Leave to Amend and Supplement its Complaint and for Substitution of Party [Doc. #106], EPA's Motion, with consent, for Leave to Amend its Answer [Doc. #73], Syngenta's Motion to Dismiss all Claims against TRI and for the Withdrawal of TRI from the Case [Doc. #80], Drexel's Motion for Joinder to Defendant EPA's Motion for Partial Dismissal of Complaint and Defendant Sipcam's Motion to Dismiss Syngenta's Third and Fourth Claims for Relief [Doc. #58], and EPA's Motion for Supplementation of the Administrative Record [Doc. #76]. The remaining pending motions will be addressed in future memorandum opinions.

Syngenta's Motion to Dismiss all Claims against TRI and for the Withdrawal of TRI from the Case is unopposed and will be GRANTED.<sup>1</sup> This Court allows Drexel to join the motions to dismiss by EPA and Sipcam [Docs. #48 & 52] and to adopt the accompanying briefs filed by EPA and Sipcam. Therefore, Drexel's Motion for Joinder will be GRANTED. Also, EPA's Motion for Supplementation of the Administrative Record is unopposed and will be GRANTED.

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<sup>1</sup>As discussed in more detail below, TRI was originally named as a Defendant in this action because some of the disputed registrations were transferred to TRI. However, as those registrations were eventually transferred back, TRI does not currently hold any of the disputed registrations, and therefore Syngenta's Motion to Dismiss the Claims against TRI will be granted.

Further, for the reasons stated below, Syngenta's Updated Motion for Leave to Amend and Supplement its Complaint will be GRANTED in full. As a result, two motions will be rendered MOOT: (1) Syngenta's previous Motion for Leave to Amend and Supplement its Complaint and for Substitution of Party, and (2) EPA's Motion for Leave to Amend its Answer.<sup>2</sup>

I.

The background facts surrounding this dispute are provided below. Part A addresses the general procedures for registering a pesticide under The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136, et seq. Part B addresses the parties and the particular pesticide registrations at issue.

A.

FIFRA governs the sale, distribution, and use of pesticides. In general, FIFRA requires that a pesticide be registered with EPA before it can be sold or distributed. FIFRA § 3(a), 7 U.S.C. § 136a(a). As part of the FIFRA registration process, an applicant must meet EPA's data requirements by submitting numerous scientific studies showing that the use of the pesticide in question will not cause unreasonable adverse effects to humans or the environment. Whether or not unreasonable adverse effects are posed is determined through reference to the

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<sup>2</sup>Syngenta's previous Motion for Leave to Amend and Supplement its Complaint and for Substitution of Party is moot because the leave requested in that motion is encompassed in Syngenta's Updated Motion. EPA's Motion for Leave to Amend its Answer is moot because Syngenta's filing of an amended complaint automatically gives EPA the right to file a new answer.

economic, social, and environmental costs and benefits of the use of the pesticide. FIFRA § 2, 7 U.S.C. § 136(bb).

Different types of registrations are available under FIFRA. For an “unconditional” registration to be issued, an applicant must show that the pesticide will perform its intended function without unreasonable adverse effects on the environment. FIFRA § 3(c)(5)(D), 7 U.S.C. § 136a(c)(5)(D).

In addition, “conditional” registrations are available in certain situations. A conditional registration of a pesticide containing an active ingredient that is not contained in any currently registered pesticide is governed by FIFRA § 3(c)(7)(C). 7 U.S.C. § 136a(c)(7)(C). A conditional registration of a pesticide identical or substantially similar to an already registered pesticide is known as a “me-too” or “follow-on” registration, and is governed by FIFRA § 3(c)(7)(A). 7 U.S.C. § 136a(c)(7)(A). For a pesticide to receive a conditional follow-on registration, the registration of the original pesticide upon which it is based must still be active.

A follow-on applicant can meet FIFRA’s data requirements in one of three ways: (1) by providing new data, (2) by the “cite-all” method in which the applicant provides a general citation to all of EPA’s files, or (3) by the “selective cite” method in which the applicant selectively cites the data of others. See 40 C.F.R. § 152.86 (cite-all method); 40 C.F.R. § 152.90 (selective method). However, under certain circumstances, a follow-on registration may be issued to an applicant who has not yet submitted all required data. If the unconditional

registrant of the identical/similar pesticide upon which the follow-on application relies has not submitted particular required data because that data has not yet been generated, the follow-on applicant also need not immediately submit that data. FIFRA § 3(c)(7)(A), 7 U.S.C § 136a(c)(7)(A). However, the applicant must submit the data by the same date by which the original registrant must do so. Id.

A follow-on conditional registration may be issued by EPA only if the registration “would not significantly increase the risk of any unreasonable adverse effect on the environment.” Id. When making this determination, the focus should be on the amount of incremental risk. Therefore, the development of a less harmful alternative is a factor that can alter the analysis. Once a less harmful alternative is registered, it will be more difficult for a follow-on applicant to obtain registration of a pesticide that is based on the older, more harmful pesticide.

Regardless of the type of registration sought, an applicant must at least provide some data showing that the registration will not cause unreasonable adverse effects to humans or the environment. In addition, once a registration is received, the holder typically will continue to submit such studies during the life of the registration to address new scientific developments and changing EPA standards. This process is generally very costly, particularly for a registrant of a new pesticide (one not based on an already existing registration).

In recognition of the expense associated with registration of a pesticide, FIFRA includes provisions that protect proprietary rights in certain data submitted

to support an application. Specifically, FIFRA § 3(c)(1)(F)(i) provides applicants that register pesticides with new active ingredients the right to “exclusive use” of any data used to support the registration of that new ingredient. 7 U.S.C. § 136a(c)(1)(F)(i). The exclusive use protection lasts for a period of ten years, but can be extended in certain circumstances. FIFRA § 3(c)(1)(F)(ii), 7 U.S.C. § 136a(c)(1)(F)(ii). During the exclusive use period, only the original applicant may use the data. EPA must deny an application supported by exclusive use data where the applicant is not the original applicant and owner of the data or has not received the consent of the original applicant to use the data. FIFRA § 3(c)(1)(F)(I), 7 U.S.C. § 136a(c)(1)(F)(I).

FIFRA includes several provisions designed to protect a registration holder’s exclusive use rights. EPA is required to provide thirty days advance notice to the holder if his exclusive use data is relevant to another application that EPA intends to grant. 40 C.F.R. § 152.116(a). Upon request by the holder and within 30 days of the holder’s receipt of such notice, EPA must “provide the applicant’s list of data requirements and method of demonstrating compliance with each data requirement.” Id. The holder may then choose to challenge the issuance of a registration to the application through petitioning EPA in the manner outlined in 40 C.F.R. § 152.99(b) & (c). 40 C.F.R. § 152.116(b). EPA may then either accept the holder’s petition by denying the applicant’s registration or deny the holder’s petition, a final agency (EPA) action, by issuing the applicant’s registration. Id.

## B.

Plaintiff Syngenta is a manufacturer and distributor of pesticides. In 1976, Syngenta's predecessor<sup>3</sup> registered the pesticide metolachlor with EPA.

Metolachlor is a grass herbicide used to control broadleaf and annual grassy weeds in various crops, trees, and turf. To develop, register, and maintain registration for metolachlor, Syngenta conducted numerous studies at a cost of millions of dollars.

In 1996, Syngenta submitted an application to EPA for registration of a new pesticide, S-metolachlor. S-metolachlor and metolachlor are chemically similar, and are designed for the same types of application and use. However, each has a different active ingredient, and a lower application quantity of S-metolachlor can provide the same pesticidal efficacy as a higher quantity of metolachlor. S-metolachlor, as compared to metolachlor, poses less toxicity to the environment without sacrificing efficacy, and is therefore considered "reduced risk."

The application for S-metolachlor was submitted under the "reduced risk pesticide" procedures and therefore given an expedited review. See FIFRA § 3(c)(10)(B), 7 U.S.C. § 136a(c)(10)(B). Because of the expedited review process, EPA did not conclude its review of the data submitted in support of S-metolachlor before issuing Syngenta a registration. S-metolachlor had a new active ingredient, and was therefore issued a conditional registration under FIFRA § 3(c)(7)(C).

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<sup>3</sup>Syngenta is the successor-in-interest to Novartis Crop Protection, Inc. and to Ciba-Geigy Crop Protection, Inc. This Memorandum Opinion refers to this group's collective interest as "Syngenta."

Upon further review of the data submitted in support of S-metolachlor, EPA determined that certain data requirements were unfulfilled, and set deadlines for submission of such data. In response, on December 20, 1999, Syngenta submitted three ecotoxicity studies: (1) the Avian Reproductive Study of the Bobwhite Quail, (2) the Acute Myside Shrimp Study, and (3) the Fathead Minnow Life-Cycle and Early Life Stage Study.

Although EPA granted Syngenta's registration of S-metolachlor, at the time it requested that Syngenta voluntarily cancel its metolachlor registrations in order to motivate consumers to use the new, less harmful pesticide.<sup>4</sup> Syngenta complied with the request and ceased the manufacture and sale of metolachlor by September 1999. On December 27, 1999, EPA publicly announced the proposed cancellation of all metolachlor registrations and stated that the cancellation would be effective June 26, 2000. Syngenta then ceased paying the registration fees for its metolachlor registrations. Despite EPA's general practice of cancelling registrations when the appropriate fees were not paid, EPA did not respond by immediately cancelling Syngenta's metolachlor registration.<sup>5</sup>

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<sup>4</sup>Syngenta's Complaint states, "EPA . . . conditioned Syngenta's registration of S-metolachlor upon the phasing out of metolachlor." In contrast, EPA claims that "Syngenta submitted a request to voluntarily cancel its metolachlor registration." (Defs' Br. Supp. EPA's M. to Dismiss at 4.)

<sup>5</sup>EPA did not cancel Syngenta's metolachlor registration until August 12, 2002, several months after Syngenta had filed the initial Complaint in this case.



After publication of the proposed cancellation of the metolachlor registration, EPA received several applications from other companies for follow-on conditional registrations based on the active registration of metolachlor. Specifically, on January 19, 2000, Defendant Cedar applied to EPA for a follow-on registration of a metolachlor product using the cite-all method of data submission. On March 2, 2000, Syngenta filed a petition with EPA to deny Cedar's application.

On October 12, 2000, Defendant Sipcam notified Syngenta that it was seeking a follow-on registration of a metolachlor product using the selective method of data submission. On November 20, 2000, Syngenta filed a petition to deny the application.

On or about April 11, 2001, Cedar filed revised applications for one technical and two end-use metolachlor follow-on registrations. This second set of Cedar applications was based on lower metolachlor application rates than was Cedar's first application. On July 2, 2001, Syngenta filed a petition to deny the second set of applications.

On September 13, 2001, Defendant Drexel sought to obtain a registration for a new source of metolachlor using the cite-all method of data submission. This Drexel application also adopted the lower application rates that had been proposed in the second set of Cedar applications. On December 18, 2001, Syngenta filed a petition to deny Drexel's application.

## II.

### A.

On March 6, 2002, Syngenta filed a complaint in the Middle District of North Carolina requesting, among other things, a temporary restraining order and a preliminary injunction against EPA.<sup>6</sup> On March 8, 2002, a temporary restraining order was issued for ten days or until the Court dissolved the order. Hearings on the preliminary injunction were held on March 8 and from March 11 through March 13, 2002. On April 11, 2002,<sup>7</sup> the motion for the preliminary injunction was denied and the temporary restraining order was dissolved. On April 29, 2002, Syngenta filed Notice of Voluntary Dismissal without Prejudice, the case was closed, and Syngenta then filed the case now before the Court.

During the resolution of Syngenta's first complaint, EPA took action on the pending applications for follow-on registrations. Despite having assured Syngenta that it would issue a decision on its cancellation no later than it issued a decision on Cedar's applications, EPA granted Cedar's second set of applications on March 21, 2002, before having issued any decision regarding cancellation of Syngenta's metolachlor registration. Subsequently, EPA also granted the applications from Sipcam and Drexel.

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<sup>6</sup>Case No. 1:02CV171

<sup>7</sup>The Memorandum Opinion was originally filed on March 15, 2002, but amended on April 11, 2002.

**B.**

On April 29, 2002, after dismissing its first action, Syngenta initiated the case at hand by filing a Complaint against EPA, the Administrator of EPA, Cedar, Sipcam, Drexel, and TRI. TRI was named because Cedar had transferred its metolachlor registrations to TRI.<sup>8</sup> The Complaint includes seven counts: (1) Count I–Violation of FIFRA Exclusive Use Protections; (2) Count II–Arbitrary and Capricious Agency Action in Violation of the APA; (3) Count III–Action Depriving Syngenta of Due Process of Law; (4) Count IV–Action in Violation of the Equal Protection Clause; (5) Count V–Mandamus Directed to EPA to Enforce the Law; (6) Count VI–Declaratory Judgment; and (7) Count VII–Equitable Estoppel.

On July 8, 2002, EPA filed an Answer [Doc. #47] and filed a Motion to Dismiss Counts III through VII pursuant to Federal Rule of Civil Procedure 12(b) [Doc. #48]. On July 9, 2002, Sipcam filed an Answer [Doc. #51] and a Motion to Dismiss Counts III and IV pursuant to Federal Rule of Civil Procedure 12(b)(6) [Doc. #52]. On July 9, 2002, Drexel filed an Answer [Doc. #50], and later filed a Motion for Joinder to EPA's and Sipcam's motions to dismiss [Doc. #58].

On July 29, 2002, the parties agreed to a Scheduling Order. [Doc. #56]. On August 21, 2002, EPA filed a Motion to Amend its Answer. [Doc. #73].

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<sup>8</sup>On March 6, 2002, Cedar requested that its applications be transferred to TRI pursuant to 40 C.F.R. § 152.135. Two days later, Cedar filed for bankruptcy. The application was granted on March 21, 2002 and the registration issued. The transfer of the registration then became effective on April 5, 2002.

On August 30, 2002, EPA filed an unopposed Motion to Supplement the Administrative Record [Doc. #76]. On that same day, Syngenta filed a Motion for Supplementation of the Administrative Record and for Limited Discovery on Counts IV and VII [Doc. #77]. This motion is opposed by EPA and Sipcam.

On September 4, 2002, Syngenta filed an unopposed Motion to Dismiss All Claims against TRI and for the Withdrawal of TRI from the Case [Doc. #80].

On November 5, 2002, the Magistrate Judge entered an Order [Doc. #92] addressing various pending motions. The Magistrate Judge ordered EPA to produce certain documents that are in dispute. EPA claims that these documents are protected by attorney-client privilege and the attorney work product doctrine, and therefore filed Objections [Doc. #94] to the portion of the Order requiring disclosure. In response, Syngenta filed a Motion to Compel EPA's Compliance with the Order [Doc. #98]. On December 9, 2002, this Court granted a motion filed by EPA to Stay the Magistrate Judge's Order pending review of the objections. These motions remain pending before the Court and will be addressed in a future memorandum opinion.

The parties agreed to a Protective Order which was entered by this Court on December 6, 2002 and amended on January 3, 2003.

On June 20, 2003, Syngenta filed a Motion for Leave to Amend and Supplement its Complaint and for Substitution of Party [Doc. #106]. This Motion was designed to reflect events and circumstances that had occurred or become

known to Syngenta since the filing of the Complaint on April 29, 2002. This Motion, in part, requested leave to substitute Makhteshim-Agan of N.A. ("MANA"), another manufacturer of pesticides, for Defendant Cedar. Defendants EPA, Sipcam, and Drexel<sup>9</sup> filed Responses indicating they consented in part and opposed in part Syngenta's Motion. Non-party MANA filed a Response/Praecipe stating its position on being substituted into this case. [Doc. #118].

On May 14, 2004, Syngenta filed an Updated Motion for Leave to Amend and Supplement its Complaint [Doc. #120]. This Motion was intended to update the June 20, 2003 motion with events that had occurred or become known to Syngenta since the filing of that June 20, 2003 motion. Therefore, the May 14, 2004 Motion reflects all pertinent events and circumstances occurring since Syngenta filed its original Complaint in this case. This Motion seeks to address (1) additional metolachlor registrations issued by EPA; (2) the submission of additional metolachlor applications by Sipcam, Drexel, and a proposed new Defendant, Albaugh, Inc.; (3) the transfer of Cedar's original metolachlor registrations back to Cedar; and (4) other pertinent new occurrences.

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<sup>9</sup>Drexel did not file its own Response, but instead filed a Joinder in the Responses on July 14, 2003. [Doc. #110].

**C.**

The new facts<sup>10</sup> that form the basis of Syngenta's May 14, 2004 Motion primarily relate to the cancellation of Syngenta's metolachlor registration, transfers of the registration originally issued to Cedar, and new application and registrations of metolachlor. A summary of these facts is as follows.

On May 16, 2002, EPA sent Syngenta a memorandum dated March 21, 2002 that explained its reasons for issuing metolachlor registrations to Cedar, Sipcam, and Drexel. Then, on August 12, 2002, EPA cancelled Syngenta's metolachlor registration.

In August 2002, EPA approved the transfer of TRI's metolachlor registrations (which originally had been obtained from Cedar) back to Cedar. Then in February 2003, EPA approved the transfer of these registrations and Cedar's pending metolachlor applications to MANA.

After filing its original Complaint, Syngenta became aware that Defendants Drexel and Sipcam had applied for additional metolachlor registrations. In addition, Albaugh, Inc. ("Albaugh"), another pesticide manufacturer, applied to EPA for metolachlor registrations. Syngenta filed petitions with EPA to deny the applications of Drexel, Sipcam, and Albaugh on December 6, 2002, January 31, 2003, and February 27, 2003, respectively.

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<sup>10</sup>These facts pertain to events that occurred after Syngenta filed its Complaint in this case on April 29, 2002.

On December 5, 2002, May 5, 2003, October 7, 2003, October 31, 2003, and February 5, 2004 EPA issued metolachlor registrations to Drexel. On March 19, 2003, in October 2003, and on March 23, 2004, EPA issued metolachlor registrations to Sipcam. On October 10, 2003 and February 24, 2004, EPA issued metolachlor registrations to Albaugh.

Syngenta's May 14, 2004 Motion to Amend also includes new allegations regarding the standard EPA applied in issuing the disputed follow-on registrations. After Syngenta filed its Complaint, EPA produced the administrative record. Syngenta contends that it learned new facts from the record indicating that the metolachlor registrations issued to Defendants were improperly evaluated with respect to the "substantial similarity" standard.<sup>11</sup>

### III.

#### A.

Rule 15(a) of the Federal Rules of Civil Procedure provides that once a responsive pleading has been served, "a party may amend the party's pleadings only by leave of court or by written consent of the adverse party; and leave shall be given freely when justice so requires." The general standard for determining "when justice so requires" is as follows:

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<sup>11</sup>A follow-on conditional registration must be "identical or substantially similar to any currently registered pesticide . . . ." FIFRA § 3(c)(7)(A), 7 U.S.C § 136a(c)(7)(A).

In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182 (1962). The decision whether to grant leave to amend falls within the discretion of the trial court; however, "the federal rules strongly favor granting leave to amend." Medigen of Ky., Inc. v. Pub. Serv. Comm'n, 985 F.2d 164, 167-68 (4th Cir. 1993).

It is well established in the Fourth Circuit that "delay alone is not sufficient reason to deny leave to amend. The delay must be accompanied by prejudice, bad faith, or futility." Johnson v. Oroweat Foods Co., 785 F.2d 503, 509-10 (4th Cir. 1986) (citing Davis v. Piper Aircraft Corp., 615 F.2d 606, 613 (4th Cir. 1980)). As explained by the court in Davis, the Foman factors "embody a principle which focuses on prejudice or futility or bad faith as the only legitimate concerns in denying leave to amend, since only these truly relate to protection of the judicial system or other litigants." 615 F.2d at 613 (4th Cir. 1980).

An amendment would be futile if the amended claim would fail to survive a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Shanks v. Forsyth County Park Auth., 869 F. Supp. 1231, 1238 (M.D.N.C. 1994). However, leave to amend should only be denied based on futility "when the proposed amendment is clearly insufficient or frivolous on its face." Johnson, 785 F.2d at 510.



**B.**

For the reasons stated below, Syngenta's Updated Motion for Leave to Amend and Supplement its Complaint will be GRANTED in its entirety.

Syngenta advances several general arguments in support of its Updated Motion to Amend. It claims that there was no undue delay in its requests for amendments. Syngenta filed its first motion to amend on June 20, 2003, after learning of new registrations in the spring of 2003. Then it filed the updated motion to amend within months of the most recent registrations. Further, Syngenta states that the matter is still in the early stages of litigation and no discovery has taken place. It argues that it has no bad faith or dilatory purpose, and specifically, it is more timely to raise these new issues now than later, during summary judgment or at trial. Syngenta contends that its proposed amendments would not prejudice Defendants, as it is seeking to augment existing claims, not to add new claims.

This Court agrees with Syngenta that there is no bad faith motivating the request to amend, and that allowing its proposed amendments would not prejudice Defendants. This dispute remains in the early stages of litigation, a time when the potential prejudicial effects of an amendment are low. See Johnson v. Oroweat Foods Co., 785 F.2d 503, 510 (4th Cir. 1986) (stating that "prejudice can result where a proposed amendment raises a new legal theory that would require the gathering and analysis of facts not already considered by the opposing party, but

that basis for a finding of prejudice essentially applies where the amendment is offered shortly before or during trial"). As it is established Fourth Circuit law that leave to amend should be granted freely in the absence of prejudice, bad faith, or futility, each of Syngenta's proposed amendments should be allowed unless amendment would be futile.

The requests contained in Syngenta's Updated Motion for Leave to Amend and Supplement its Complaint can be broken down into the following topics: (1) substitution of MANA; (2) addition of Albaugh as a defendant; (3) new metolachlor registrations; (4) new applications and potential future applications for metolachlor registrations; (5) FIFRA's "substantial similarity" standard; (6) additional factual details including the cancellation of Syngenta's metolachlor registration, the turf grass study, and new metolachlor application rates. Each topic is discussed below.

# 1.

First, Syngenta seeks to amend its Complaint to substitute MANA for Defendant Cedar. The metolachlor registrations originally issued to Cedar were transferred to MANA in February 2003, almost one year after Syngenta filed its Complaint. There are no objections to an amendment reflecting such a substitution and no suggestions of futility. Therefore, Syngenta will be granted leave to substitute MANA for Cedar in its Amended Complaint.

**2.**

Second, Syngenta seeks to amend its Complaint to name Albaugh as an additional defendant. Albaugh has applied for and received metolachlor registrations since the date Syngenta filed its Complaint. Again, there are no objections to an amendment adding Albaugh and no suggestions of futility. Therefore, Syngenta will be granted leave to add Albaugh as a defendant in its Amended Complaint.

**3.**

Third, Syngenta seeks to amend its Complaint to reflect the additional metolachlor registrations issued by EPA since the date the Complaint was filed. In particular, additional metolachlor registrations were issued to Drexel, Sipcam, and Albaugh. As there are no objections to this amendment and no suggestions of futility, Syngenta will be granted leave to amend its Complaint to reflect the additional metolachlor registrations.

**4.**

Fourth, Syngenta seeks to amend its Complaint to add language requesting that the Court enjoin EPA from issuing any more metolachlor registrations on the same grounds as those already issued. Specifically, Syngenta seeks to enjoin registrations that would result both from currently pending applications and from any future applications that may be filed.

Sipcam and EPA oppose this amendment on futility grounds. Specifically, they argue that this Court previously found EPA action with respect to registrations not yet issued not to be “final agency actions.” Syngenta Crop Protection, Inc. v. EPA, 202 F. Supp. 2d 437, 446-48 (M.D.N.C. 2002). Therefore, challenges to such actions would be unripe and not survive a motion to dismiss.

However, the situation here is different from the situation existing at the time this Court’s previous opinion in this matter was filed. Here, Syngenta has already properly brought claims that are ripe for review before the Court. Specifically, this Court has jurisdiction to review EPA’s issuance of metolachlor registrations to the other Defendants. Given that Syngenta’s claims are properly before the Court, Syngenta may request whatever relief it wishes, including declaratory relief that would apply to future applications.<sup>12</sup> Further, some of the contested language regarding Syngenta’s request for declaratory relief is already present in the original Complaint filed in this matter. In short, Syngenta will be granted leave to amend its Complaint by adding language requesting that the Court enjoin EPA from issuing further metolachlor registrations.

## 5.

Fifth, Syngenta seeks to amend its Complaint to add allegations that EPA improperly applied FIFRA’s “substantial similarity” standard. The parties disagree

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<sup>12</sup>Whether or not that relief should ultimately be granted is not presently a relevant consideration.

as to whether, in the context of determining the terms of the Protective Order, Syngenta previously agreed that issues of substantial similarity would not be relevant. Even if Syngenta had previously agreed to this, absent any claims of prejudice to Defendants, it is not clear why Syngenta should not be allowed to change its position based on information discovered since the filing of the Complaint. Therefore, leave to amend the Complaint to include assertions regarding the substantial similarity standard will be granted.

**6.**

Finally, Syngenta seeks to amend its Complaint to add language reflecting additional factual assertions, specifically, details regarding the circumstances surrounding EPA's ultimate cancellation of Syngenta's metolachlor registration, a turf dissipation study, and metolachlor efficacy and application rates. Sipcam contests these proposed amendments on the grounds of futility. At most, Sipcam is objecting to the addition of facts which it contends are irrelevant. Syngenta is not attempting to add potentially futile new claims, only facts. Therefore, absent prejudice to the Defendants, such factual amendments should be allowed. Therefore, leave to amend the Complaint to include these additional factual assertions will be granted.

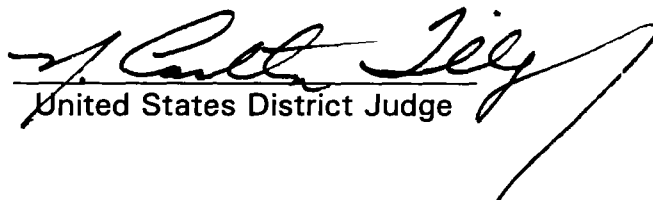
**IV.**

In conclusion, Syngenta's Updated Motion for Leave to Amend and Supplement its Complaint [Doc. #120] will be GRANTED in full. Therefore, the

following two motions will be rendered MOOT: Syngenta's previous Motion for Leave to Amend and Supplement its Complaint and for Substitution of Party [Doc. #106], and EPA's Motion for Leave to Amend its Answer [Doc. #73]. After Syngenta files its Amended Complaint, Defendants will each have the right to file a response pursuant to Federal Rule of Civil Procedure 15(a). Any Defendant that so wishes may also file a revised motion to dismiss.

Syngenta's Motion to Dismiss all Claims against TRI and for the Withdrawal of TRI from the Case [Doc. #80] is unopposed and will be GRANTED. Drexel's Motion for Joinder [Doc. #58] will be GRANTED. Finally, EPA's Motion for Supplementation of the Administrative Record [Doc. #76] will be GRANTED.

This 12<sup>th</sup> day of July, 2004

  
United States District Judge